AUG 2 7 2001

K011715

ADMINISTRATIVE INFORMATION

Manufacturer Name:

MacroPore, Inc.
6740 Top Gun Street
San Diego, CA 92121

Official Contact:

Kenneth K. Kleinhenz
Director of Regulatory Affairs

DEVICE NAME

Classification Name:

Hip Joint Cemented Prosthesis

Trade/Proprietary Name:

MacroPore *IB* Resorbable Plug

ESTABLISHMENT REGISTRATION NUMBER

2031733

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21CFR 888.3350 Hip Joint Cemented Prosthesis are intended for use in orthopedic cementing procedures and are classified as Class II. Hip Joint Cemented Prosthesis have been assigned Product Code JDK.

INTENDED USE

MacroPore *IB* Resorbable Plug is indicated for use as a cement restrictor in the femur, tibia and humerus.

DEVICE DESCRIPTION

Design Characteristics

MacroPore *IB* Resorbable Plug is a resorbable implant manufactured from poly lactic acid (PLA). The MacroPore *IB* Resorbable Plug is designed to wedge into the inter medullary region of long bones to restrict the flow of cement. The MacroPore *IB* Resorbable Plug is fully malleable when heated to approximately 55°C (for example, by the use of sterile hot water), and thus can be conformed three dimensionally to most any anatomical orientation.

MacroPore *IB* Resorbable Plug is provided in various shapes such as rectangles, ovals, and cylinders and will be provided in other similar shapes and sizes as needed for particular surgical procedures. The wall thickness of the MacroPore *IB* Resorbable Plug ranges from 0.5 mm to 4.0 mm according to the region to be treated. The major outer diameter of the MacroPore *IB* Resorbable Plug ranges from 4mm to 30mm according to the region to be treated. A minimum of two sides of the MacroPore *IB* Resorbable Plug contain fenestrated edges to assure a secure fit within the inter medullary region and to prevent dislodging. These fenestrated edges also allow for a secure fit between segmental defects.

Material Composition
The MacroPore *IB* Resorbable Plug is fabricated from polylactic acid (PLA).

In Vitro Testing
Because the MacroPore *IB* Resorbable Plug is intended to be heated in the surgical suite to temperatures above the material's glass transition temperature to facilitate shaping to anatomic structures, testing was performed to determine the effect of prolonged heating in saline at 60°C on inherent viscosity. The testing demonstrates that viscosity stayed within an appropriate range over 120 minutes. Therefore, the relatively brief exposure anticipated during the surgical preparation of MacroPore *IB* Resorbable Plug is not expected to have a significant effect on its mechanical properties.

Crystallinity was tested for by DSC (differential scanning calorimetery). This test measures the amount of heat energy that is absorbed by a material. A crystalline material will require more energy once it reaches it's melting point. This release of heat energy can be seen on a graph as a sharp spike and is referred to as a "melting endotherm". The tests ran on the sterile and non-sterile samples revealed no endothermic spikes, confirming the amorphous (non-crystalline) nature of the implants.

EQUIVALENCE TO MARKETED PRODUCT

MacroPore *IB* Resorbable Plug shares indications and design principles with the following predicate device, which has been determined by FDA to be substantially equivalent to the following pre- amendment devices: Medtonic Sofamor Danek Cement Restrictor, Medtronic Sofamor Danek Titanium Cement Restrictor, and the MacroPore *OS* Protective Sheet, Class II medical device that were cleared for marketing in the United States under K010529, K003718 and K994158 respectively.

Indications For Use
The MacroPore *IB* Resorbable Plug and the predicate device share substantially equivalent indications for use as they both are indicated for cement restriction. Specifically, the MacroPore *IB* Resorbable Plug is intended for use as a cement restrictor in the femur, tibia and humerus.

Design and Materials
The MacroPore *IB* Resorbable Plug and the predicate device share substantially equivalent design features, principles of operation, and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 4 2001

Mr. Kenneth K. Kleinhenz
Director of Regulatory Affairs
MacroPore, Inc.
6740 Top Gun Street
San Diego, California 92121

Re: K011715
Trade Name: MacroPore IB Resorbable Plug
Regulation Number: 888.3350
Regulatory Class: II
Product Code: JDI
Dated: June 1, 2001
Received: June 4, 2001

Dear Mr. Kleinhenz:

This letter corrects our substantially equivalent letter of August 27, 2001.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's package insert and also as a Warning on the product label:

WARNING: THIS DEVICE IS NOT INTENDED FOR ANY SPINAL INDICATIONS. THE SAFETY AND EFFECTIVENESS OF THIS DEVICE WHEN IMPLANTED IN THE SPINE HAVE NOT BEEN ESTABLISHED.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

Device Name: **MacroPore *IB* Resorbable Plug** K011715

Indications for Use:

MacroPore *IB* Resorbable Plug is indicated for use as a cement restrictor in the femur, tibia and humerus.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes OR Over-The-Counter Use No

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011715